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Patent
Attorney's Docket No. 033123-005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of)
U.S. Patent No. 4,981,784)
Ronald M. Evans et al) Group Art Unit: 2736
Application No.: 09/773,041) Examiner: Unassigned
Filed: January 31, 2001)
For: CHIMERIC STEROID HORMONE)
SUPERFAMILY RECEPTOR)
PROTEINS)

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DECLARATION UNDER 37 C.F.R. §1.175

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Petitioner, through the undersigned, declares that Petitioner is a not-for-profit corporation existing under the laws of California, having a place of business in La Jolla, California, and is the owner of the entire right, title and interest in and to United States Letters Patent No. 4,981,784, granted January 1, 1991, and entitled "RETINOIC ACID RECEPTOR METHOD."

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Petitioner further declares the following:

Petitioner verily believes United States Letters Patent No. 4,981,784 may be at least partly inoperative for the reason that Petitioner failed to provide claims of more narrow scope.

This error in claiming was brought to Petitioner's attention during Interference No. 104,583.

This application for reissue of the original Letters Patent addresses the above-identified error by adding additional claims further defining the invention of Evans et al. More specifically, the added claims are narrower in that they include independent claims which specify the specific members of the steroid superfamily of receptors from which the N-terminus, DNA-binding and ligand-binding domains are selected. It was error for Petitioner to omit claims of this scope.

These claims are fully supported by the specification for the '784 Patent. Illustrative support for the added claims is as follows:

12. A method for identifying functional ligands for receptor proteins {**Column 1, lines 23-25; Column 11, lines 53-54**}, said method comprising:
 - (a) isolating DNA sequences having a ligand-binding domain and a DNA-binding domain {**Column 11, lines 54-64**};
 - (b) constructing a chimeric gene by substituting operative portions of the DNA-binding domain region of the DNA sequence of step (a) with operative

portions of a DNA-binding domain region from a known ligand-responsive receptor protein selected from the group consisting of hGR, hMR, hERR₁, hERR₂, rTR α , hT₃R α , hT₃R β , hRAR α 1 and hRAR β {Column 11, line 64 - Column 12, line 3};

- (c) introducing into a suitable receptor-deficient host cell: (1) the chimeric gene from step (b), and (2) a reporter gene functionally linked to an operative hormone response element wherein the hormone response element is capable of being activated by the DNA-binding domain region of the receptor protein encoded by the chimeric gene of step (b) and is selected from the group consisting of wild-type, recombinantly produced or synthetic GR, PR, ER, T₃R β and V-erbA response element {Column 3, lines 63-68; Column 5, lines 1-48; Column 12, lines 3-24};
- (d) challenging the transfected host cell from step (c) with at least one compound to be evaluated for ligand binding activity with the chimeric receptor protein encoded by the chimeric gene of step (b) {Column 12, lines 24-28};
- (e) monitoring induction of the reporter gene {Column 12, lines 28-34}; and
- (f) identifying as a functional ligand(s) that ligand(s) which is capable of inducing production of the protein product of the reporter gene {Column 12, lines 35-38}.

13. A method according to claim 12 wherein the glucocorticoid response element is

encompassed within the mammary tumor virus long terminal repeat sequence (MTV LTR) {Column 13, line 66 - Column 14, line 2}, and the thyroid response element is encompassed within the growth hormone promoter sequence {Column 14, lines 23-34}.

14. A method for identifying functional ligands for receptor proteins in a cell {Column 11, lines 53-54} wherein said cell contains: (a) an expressible chimeric DNA sequence (c) comprised of operative portions of a DNA-binding domain of a first receptor sequence linked to operative portions of a ligand-binding domain of a second receptor sequence {Column 12, lines 43-49}, wherein said first and second receptor sequences are selected from the group consisting of sequences from hGR, hMR, hERR₁, hERR₂, rTR α , hT₃R α , hT₃R β , hRAR α 1 and hRAR β {Column 11, lines 23-36}, and (b) a reporter nucleic acid sequence functionally linked to an operative hormone response element {Column 12, lines 49-51} wherein said chimeric DNA sequence is expressed and wherein the DNA-binding domain of the chimeric receptor protein thus produced can functionally bind to and activate the hormone response element that is functionally linked to the reporter sequence {Column 12, lines 51-55}, wherein the hormone response element is selected from the group consisting of wild-type, recombinantly produced or synthetic GR, PR, ER, T₃R β and V-erbA response element {Column 3, lines 63-68; Column 5, lines 1-48; Column 12, lines 3-24}; said method comprising challenging the cell with at least one compound to be evaluated for ligand binding activity wherein said compound to be evaluated is not known to be a functional ligand for the chimeric protein encoded by said chimeric DNA sequence (c) {Column 12, lines 55-64}.

15. A method according to claim 14 wherein the glucocorticoid response element is encompassed within the mammary tumor virus long terminal repeat sequence (MTV LTR) {Column 13, line 66 - Column 14, line 2}, and the thyroid response element is encompassed within the growth hormone promoter sequence {Column 14, lines 23-34}.

The aforementioned error in claiming occurred without any deceptive intention on Petitioner's part. On information and belief, all errors being corrected in the Reissue Patent Application arose without any deceptive intention on the part of the applicant.

Petitioner verily believes that the named inventors, Ronald M. Evans, residing at 1471 Cottontail Lane, La Jolla, CA 92037, a citizen of the United States; Estelita S. Ong, residing at 6307 Hannon Ct., San Diego, CA 92117, a citizen of the United States; Prudimar S. Segui, residing at 10833 NE 149th St., Bothell, WA 98011, a citizen of the United States; Catherine C. Thompson, residing at 503 Wingate Rd., Baltimore, MD 21210, a citizen of the United States; Kazuhiko Uemsono, now deceased; and Vincent Giguere, residing at 277 Querbes, Outremont, H2V 3W1 Canada, a citizen of Canada; to be the first, original and joint inventors of the subject matter which is described and claimed in the specification and claims of the present Reissue Patent Application. Petitioner does not believe that the invention was ever known or used before the above-named inventors' invention thereof was made.

Petitioner has reviewed and understands the contents of the specification, including

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the claims as presented in the instant application for reissue.

Petitioner acknowledges the duty to disclose information of which Petitioner is aware and which is material to the examination of this application for reissue, in accordance with 37 C.F.R. § 1.56(a).

The undersigned hereby declares further that all statements made herein of his own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

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